DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
Endoscopy Division
Ms. Janice Haselton
Regulatory Affairs Specialist
160 Dascomb Road
Andover, MA 01810

JUL 27 2015

Re: K003710
Trade/Device Name: Dynonics Vision 337 Autoclavable Camera Head and Camera Coupler
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET, GCJ
Dated (Date on orig SE ltr): November 30, 2000
Received (Date on orig SE ltr): December 1, 2000

Dear Ms. Haselton,

This letter corrects our substantially equivalent letter of February 2, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number : K003710

Device Name : Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler

Indications for Use :

The Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler are indicated for use in endoscopic surgical procedures to provide illumination and allow visualization of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

Additionally, the Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler are indicated for use in endoscopic surgical procedures in the thoracic cavitity when used in conjunction with an appropriately indicated thoracoscope.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003710

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

FEB - 2 2001

K003710

Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 978-749-1000
Telefax: 978-749-1599

Smith+Nephew

510(k) Summary
Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler
Date Prepared: November 30, 2000

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact
Janice Haselton
Regulatory Affairs Specialist

C. Device Name

Trade Name:	Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler
Common Name:	Camera Head and Camera Coupler
Classification Name:	Endoscope and/or Accessories

D. Predicate Devices
Dyonics Digital 3-Chip Color Video Camera K972471
Dyonics DyoCam Video Camera K914919
Dyonics Camera Coupler K972471

E. Description of Device
The proposed Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler can be used in conjunction with any direct-view endoscope or appropriate video-endoscope, control unit, light source, and monitor to allow illumination and visualization of articular cavities, body cavities, hollow cavities and canals. The camera head acts to transmits real time video images of the surgical site to the camera control unit. It then processes and displays the image to a viewing system or recording media.
The camera head attaches to the endoscope by means of a camera coupler.
The camera head and the camera coupler are hermetically sealed to allow for autoclavability.

F. Intended Use

The Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler are indicated for use in endoscopic surgical procedures to provide illumination and allow visualization of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

Additionally, the Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler are indicated for use in endoscopic surgical procedures in the thoracic cavity when used in conjunction with an appropriately indicated thoracoscope.

G. Comparison of Technological Characteristics

The Dyonics Vision 337 Autoclavable Camera and Camera Coupler are substantially equivalent in design, materials of construction, and function and intended use as to the Smith & Nephew Images Digital 3-Chip Color Video Camera and Dyonics Camera Coupler.

Janice Haselton

Regulatory Affairs Specialist